

**Secondary Direct Food  
Additive Petition**

**Acidified Solutions of Sodium  
Chlorite/Chlorous Acid for  
Red Meat Parts Disinfection  
in Processing Plants**

**FAP No. 9A4692**

**AMENDMENT 001**

**Revised: October 8, 1999**

**Alcide CORPORATION**

8561 154<sup>th</sup> Avenue NE - Redmond, WA 98052  
Telephone: 425/882-2555 Fax: 425/861-0173

99F-2907

EA-2  
~~EA-1~~

# Alcide CORPORATION

8561 154th Avenue NE, Redmond, WA 98052 425-882-2555 Fax: 425-861-0173

October 8, 1999

Dr. Robert L. Martin  
U.S. Food and Drug Administration  
Center for Food Safety and Applied Nutrition  
Office of Premarket Approval  
HFS-215  
200 C Street, SW  
Washington, DC 20204

RE: Food Additive Petition No: 9A4692 – Section §171.1(c)(H) – Environmental Assessment  
Amendment 001 – Revised: October 8, 1999

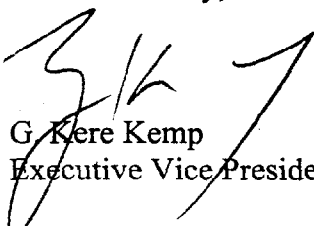
Dear Dr. Martin:

Reference to Dr. Kross's telephone discussion with Ms. Jeanette Glew on September 29 and subsequent to her email of September 30, 1999. Please find enclosed 3 copies of the revised petition modified according to the requirements detailed in Ms. Glew's email of September 30, 1999.

Revised Page: A-0001	Item 1.0	New date for the revised submission.
Revised Page: A-00016	Item 6.2	A general statement is added to the effect that no extraordinary circumstances exist at the site of production of the subject additive.
Revised Page: A-00024	Item 8.1	Correction to the maximum level of sodium chlorite as 5 ppb.
Revised Page: A-00024	Item 8.1	A general statement is added about the potential for environmental effects and the need for any mitigation measures not entirely confined to potential effects in the workplace.
Revised Page: A-00032	Item 13.0	New date of submission of the Environment Assessment and signature of company official.
Revised Page: A-00033	Item 14.0	Material Safety Data Sheet for Concentrate Chlorite is added. (Pages: A-00038 to A-00045)

Please let me know if any addition information or changes are required.

Yours sincerely,

  
G. Kere Kemp  
Executive Vice President

cc: Operations Committee  
Dr. R. Kross

## **§171.1(c)(H) ENVIRONMENTAL ASSESSMENT**

### **Section Contents**

- 1.0 DATE: October 8, 1999**
- 2.0 PETITIONER: Alcide Corporation**
- 3.0 ADDRESS: 8561 154th Avenue, NE  
Redmond, WA 98052**
- 4.0 DESCRIPTION OF THE PROPOSED ACTION**
- 5.0 IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE  
SUBJECT OF THE PROPOSED ACTION**
- 6.0 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT**
- 7.0 FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT**
- 8.0 ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES**
- 9.0 USE OF RESOURCES AND ENERGY**
- 10.0 MITIGATION MEASURES**
- 11.0 ALTERNATIVES TO PROPOSED ACTION**
- 12.0 PREPARER**
- 13.0 CERTIFICATION**
- 14.0 APPENDICES**
- 15.0 BIBLIOGRAPHY**

Revised: October 8, 1999

## **4.0 DESCRIPTION OF THE PROPOSED ACTION**

### **4.1 REQUESTED APPROVAL**

Approval is requested for the use of acidified sodium chlorite (ASC) solutions to reduce microbial pathogens on the surfaces of red meat cuts, organ meats and related specialty cuts, for use *per se* or prior to their being ground into chopped meat and/or related comminuted meat products. The identically formulated solutions are currently approved under 21CFR §173.325 for use as an antimicrobial carcass spray agent in the processing of red meat.

There are two components used to create these solutions, the food-grade acid and the sodium chlorite. Sufficient acid is added to a 500 - 1,200 parts per million (ppm) solution to reduce its pH to the 2.5 - 2.9 range. The resulting acidified sodium chlorite solutions are then applied to the meat surfaces as either a spray or a dip. In the former case, the liquid is dispensed from a spray apparatus in which either i) two streams of the chlorite and the acid solutions are mixed at, or immediately before the spray nozzle, or ii) a single stream of acidified chlorite is directed to the spray nozzle from a pre-mixed solution. The latter may be prepared up to 8-hours prior to spraying, preferably in cold water, so long as the chlorite and acid levels have been analytically determined to be within acceptable levels. When the antimicrobial solution is applied as a dip, the meat pieces are immersed in the dip solution for a brief period of time, generally 10 to 30 seconds. Following both spray and dip application, the meat pieces are rinsed with water to remove the applied solution.

### **4.2 NEED FOR THE ACTION**

There is still a strong need for good hygienic practices after the initial post-slaughter decontamination of red meat carcasses, in order to ensure the unbroken microbiological safety and quality of the subprimal, secondary and retail meat cuts and specialty meats. Of particular importance are the comminuted meat products, in which any pathogenic organisms

Revised: October 8, 1999

F:\R&D\700 REGULATORY\754 BEEF\ANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)environmental assessment-amendment 001.doc Page 2 of 34

**A-0002**

that were initially present on the surface of the meat pieces become intimately combined with the ground product. Unless proper temperatures are achieved during the cooking of the comminuted meat to destroy the pathogens, they can survive and cause illness or death to the consumer.

Millions of Americans become ill each year from something they eat. This number can only be approximated by government officials, who indicate that less than 5 percent of food illnesses are ever reported to authorities, and must therefore rely heavily on estimates when quantifying the problem. The Centers for Disease Control and Prevention calculates that *E. coli* O157:H7 alone infects up to 20,000 Americans a year through contaminated meat, produce and other sources. Of these up to 500 may die. A 1987 survey of retail meats from grocery stores in Madison, WI found that *E. coli* O157:H7 could be isolated from approximately 2% of beef, poultry, pork and lamb samples. A more recent example occurred in mid-1997, when the US suffered its most widespread food scare and the biggest product recall in history. The Hudson Foods Company was forced to recall 25 million pounds of frozen minced beef after an outbreak of food poisoning in Colorado was traced to meat contamination with *E. coli* O157:H7 from one of its well-inspected, up-to-date plants. Most recently, in 1998, Iowa Beef Packers received some contaminated beef in its Illinois plant, and the resulting ground product caused outbreaks of *E. coli* O157:H7 in Florida and Georgia.

Although this particular pathogenic organism has been the center of attention in recent years, there are many well known organisms which tend to be less lethal, but nonetheless are the main source of most of the sicknesses and occasional deaths that arise from pathogen-bearing comminuted meat products. Pathogens can be recovered from beef and other red meats, as well as meat specialty cuts such as tongue, liver and intestines, in meat-handling facilities where good hygiene is not always sufficient to eliminate them completely. These pathogens, include various *Salmonella* species, *Listeria monocytogenes*, *Staphylococcus aureus* and *Campylobacter jejuni*. These pathogens often require additional means to diminish or eliminate their numbers than the customary surface rinsing, or simple wiping which meat pieces sustain. It is the position of the Alcide Corporation that the

acidified sodium chlorite solutions which are the subject of this Food Additive Petition, and which have already been approved by the FDA for use in both poultry and red meat carcass processing, can play a major role in upgrading the microbial quality of the primary and secondary meat cuts, organs and related meat parts, particularly those materials which are further processed into the U.S. ground meat supply.

#### **4.3 LOCATIONS WHERE PRODUCTS WILL BE PRODUCED**

There are two components to the acidified chlorite solutions being proposed for Secondary Direct Food Additive Status, the sodium chlorite and the acidifier needed to achieve the desired solution pH. The acidifier can be any one of a variety of FDA-approved GRAS acids, including phosphoric, sulfuric, malic, acetic and citric. These are all materials of very high volume usage, and of many current diverse applications. The projected volumes of use as an activator of sodium chlorite are much below a fractional percentage of the other applications. Thus the sites of production of these different acids is not considered relevant to this environmental assessment.

Sodium chlorite is currently being used as a chlorine dioxide ( $\text{ClO}_2$ ) source in water treatment, as well as an industrial bleaching agent in a number of industries (primarily pulp and paper), in cleaning applications for the electronics industry, as a biocide in the food processing industry, and in various applications in the oil industry. On April 23, 1996 the U.S. FDA approved the use of sodium chlorite as a component of acidified sodium chlorite solutions for pathogen reduction in poultry processing. Thereafter, in a similar action on February 27, 1998, the FDA allowed for the use of ASC solutions in red meat carcass sprays. The current size of the North American market for sodium chlorite is about 20 million lb. per year, slowly growing primarily at the expense of chlorine. The major production source has been the Vulcan chemicals facility in Wichita, which has a production capacity of about 22 million lb per year. About 50% of that sodium chlorite is directed towards drinking water disinfection in the United States. Sterling Chemicals, of Houston, Texas, along with its Tenneco's production facility in Richmond, Virginia, contribute to the total 11 million lb per year sodium chlorite manufacturing capacity ex. Buckingham, Quebec. Other foreign

Revised: October 8, 1999

FAR&D\700 REGULATORY\754 BEEF\ANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)\environmental assessment-amendment 001.doc Page 4 of 34

**A-0004**

production sites for sodium chlorite, which may be accessed if quality and economics are appropriate, include that of France's Atochem, S.A., the world's largest product and Energia Industrias Aragonesas, Madrid, Spain.

#### **4.4 LOCATIONS WHERE THE PRODUCTS WILL BE USED**

The annual beef and veal consumption of the United States in 1996 was 11.7 million metric tons, with a pork consumption of 8.3 million metric tons. This equates to an annual per capita consumption of 64.2 pounds of beef, 1.0 pounds of veal, and 46.1 pounds of pork<sup>1</sup>. Of this, the American Meat Institute estimates that about 50% of the red meat consumed in this country is as ground product<sup>1</sup>. This ground product primarily encompasses the meat used in hamburger, ground beef and sausage. Hamburger meat is ordinarily a blend of beef and less expensive cuts, including fat up to 30%. Some ground beef, which can also contain up to 30% fat, can be produced and packaged at USDA-inspected plants. Both products must be labeled in accordance with the Federal Standards and Labeling Policy, and marked with a USDA label. The Food Safety and Inspection Service carries out the USDA's responsibilities under the Federal Meat Inspection Act.

All meat that is transported and sold in interstate commerce must be federally inspected. For meat that is being transported and sold within a state, state inspection then applies. State inspection programs must enforce requirements at least equal to those of the Federal inspection laws. The larger cuts are usually shipped to local stores, where it is ground. Most ground beef is ground and packaged in local stores rather than in food processing plants under USDA inspection. Yet most of the reported pathogen-induced meat outbreaks appear to be associated with hamburger produced in central distribution points. For example, in the Jack-In-The-Box incident, the hamburger was produced in a contract patty-making operation using meat from several sources, and the ground product then shipped to local outlets. The Hudson Foods and Iowa Beef Packers incidents are also examples of centralized production, using meat sources from many locations. No matter how well-inspected and modern an operation, the basic problem is that grinding exposes more of the meat, whose interiors are normally sterile, to microbial contamination from the

Revised: October 8, 1999

air, the meat surface itself, butchers' hands and cutting equipment. This pathogen contamination is not immediately detectable; and bacteria can multiply in temperature ranges between 40° F and 140° F, with *E. coli* 0157:H7 capable of growth from 44° F upwards.

Once the pending Food Additive Petition is accepted as a regulation, the acidified chlorite antimicrobial will become available to all central processing plants in the United States as well as local supermarkets and butchers. Generally the central processing plants are located in the same geographic areas as the abattoirs. According to the American Meat Institute, the following States contain the highest percentages of such plants among its member companies.

RANK	STATE	PERCENT
1	Kansas	20
2	Nebraska	19
3	Texas	18
4	Colorado	7
5	Iowa	5
6	Wisconsin	4
7	Minnesota	3
8	Pennsylvania	2.9
9	California	2.6
10	Washington	2.5

Other red meat processors are located in Illinois, Indiana, Ohio, Michigan, North Dakota, South Dakota, Missouri, Tennessee, Virginia, North Carolina, South Carolina, Georgia, Florida, Arkansas and Oklahoma. Few plants are found in the North East and West, other than in California and Washington.

It is difficult to obtain an estimate of the hamburger, ground beef and sausage that is produced locally, but it appears from the above information that the predominance of comminuted meat production will focus in the central U.S. states, with local production

Revised: October 8, 1999



accounting for somewhat less usage in the eastern and far-western states. The projected usage of the petitioned ASC solutions will generally correspond in volume to the production site locations described above.

**Revised: October 8, 1999**

FAR&D\700 REGULATORY\754 BEEF\ANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)environmental assessment-amendment 001.doc Page 7 of 34

**A-0007**

## **5.0 IDENTIFICATION OF CHEMICAL SUBSTANCES THAT ARE SUBJECT OF THE PROPOSED ACTION**

### **5.1 CHEMICAL NAMES AND PHYSICAL PROPERTIES**

#### **5.1.1 Sodium Chlorite**

CAS Reg. No.: 7758-19-2  
Color (37% Solution): Colorless to light green  
Specific Gravity: 1.21  
Viscosity (@25°C): 1.62 cps  
pH: 12.33

#### **5.1.2 Acidifiers (GRAS)**

##### **Phosphoric Acid**

CAS Reg. No.: 7664-38-2  
Conforms with 21CFR §182.1073 as a Multiple Purpose GRAS Food Substance

##### **Citric Acid**

CAS Reg. No.: 77-92-9 (anhydrous)  
5949-29-1 (monohydrate)  
Conforms with 21CFR §182.1033 as a Multiple Purpose GRAS Food Substance

## **Hydrochloric Acid**

CAS Reg. No.: 7647-01-0

Conforms with 21CFR §182.1057 as Multiple Purpose GRAS Food Substance

## **Malic Acid**

CAS Reg. No.: 617-48-1 DL mixture

97-67-6 L isomer

Conforms with 21CFR §184.1069 as a Specific Substance Affirmed as GRAS, with respect to the following ¶s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

## **Sulfuric Acid**

CAS Reg. No.: 7664-93-9

Conforms with 21CFR §184.1095 as a Specific Substance Affirmed as GRAS, with respect to the following ¶s,

- (a) description
- (b) specifications
- (c) use as pH control agent
- (d) maximum use level

## Acetic Acid

CAS Reg. No.: 64-19-7

Conforms with 21CFR §184.1005 as a Specific Substance Affirmed as GRAS, with respect to the following ¶s,

- (a) description
- (b) specifications
- (c) use as a pH control agent
- (d) maximum use level

The subject of this food additive petition (FAP) is the system comprised of acidified aqueous sodium chlorite solutions for use as an antimicrobial agent to reduce pathogenic microorganisms on organs and red meat cut surfaces, particularly those subject to subsequent comminution or grinding into such items as hamburger patties, ground beef or sausage. The composition and concentration of the system depends on the mode, site of application of the antimicrobial solution (*e.g.*, large processing facility, supermarket) and quantity of meat being processed.

## 5.2 MODE OF ACTION OF THE GERMICIDAL SYSTEM

The germicidal activity of this antimicrobial system derives from the degradation of chlorous acid ( $\text{HClO}_2$ ; CAS No. 13898-47-0) which will form as a predictable fraction of the total chlorite species ( $\text{ClO}_2^-$ ) in the solution. The degree to which chlorous acid forms will depend on the hydrogen ion concentration (*i.e.* pH) of the solution. Chlorous acid, an unstable material, can exist in equilibrium with the chlorite ion in aqueous systems with a stability proportionate to its total concentration; the lower the concentration the slower the rate of degradation.

Revised: October 8, 1999

F:\R&D\700 REGULATORY\754 BEEFANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)environmental assessment-amendment 001.doc Page 10 of 34

A-00010

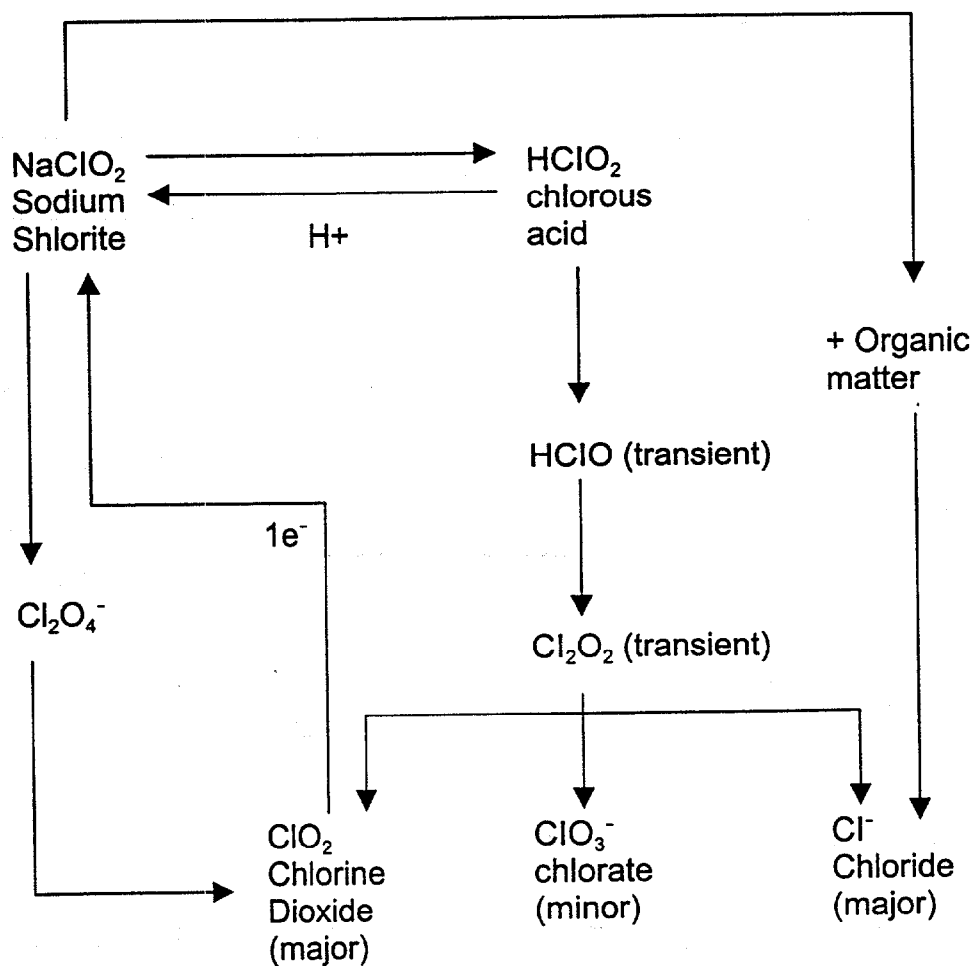
Chlorous acid has a  $pK_a$  of  $1.1 \times 10^{-2}$ , and from this constant the relative amount of chlorous acid can be calculated for the pH range of intended application of this acidified sodium chlorite system. At the petitioned range of pH's, 2.5 - 2.9, the chlorous acid levels, as percentages of total chlorite ion, are as follows:

pH	% Chlorite as $\text{HClO}_2$
2.5	22.2
2.6	18.1
2.7	15.0
2.8	12.3
2.9	10.0

To achieve these solution pH values, different quantities of the individual GRAS acids are required, depending on their strength and buffering action needed. This can range from *ca.* 0.01% for a mineral acid to ~1.5 - 2.5% level of acetic acid.

The ability to provide sustained antimicrobial activity based on the presence of chlorous acid relies on the presence of reservoirs of chlorite and hydrogen ions in the solution. As the chlorous acid is consumed, through interaction with microorganisms and certain other organic matter in solution, re-equilibration will occur to produce more of the acid chlorous acid. The following schematic covers the relevant aspects of this chemistry:

### Schematic of Chlorite/Chlorous Acid System



Revised: October 8, 1999

A-00012

As chlorous acid degrades it produces a series of transient oxidants, including hypochlorous acid and dichlorine dioxide; and ultimately chlorine dioxide ( $\text{ClO}_2$ ; CAS No. 10049-04-4) if the intermediates are not consumed through a redox interaction with such organic materials as microorganisms. The  $\text{ClO}_2$  that forms may further combine with free chlorite ( $\text{ClO}_2^-$ ) to form the cidal oxidant  $\text{Cl}_2\text{O}_4^-$ .

The  $\text{H}^+$  ion source can be any protic acid which, for this application, must be a GRAS material. Three such acids, covering a range of strengths, are phosphoric acid (CAS No. 7664-38-2), citric acid (CAS No. 77-92-9) and acetic acid (CAS No. 64-19-7), although these materials are representative rather than restrictive of the GRAS acids which may be employed as suitable acidifiers of the chlorite ion.

## 6.0 INTRODUCTION OF SUBSTANCES INTO THE ENVIRONMENT

### 6.1 PRODUCTION RELEASES

As noted above in Section 4, the acidified chlorite/chlorous acid solution will be produced on site immediately before application in the processing facility, be it a major operation, a contract operation for a specific chain, or a supermarket facility. The solution mixing will take place either immediately prior to, or directly during the spraying process, the latter by confluence of the separate acid activator and sodium chlorite solutions at the nozzle. In both cases the acid and sodium chlorite solutions will be prepared in cool tap water, so that during the brief time between creation and activation of the ASC solution the levels of free chlorine dioxide that are generated from the solution are not expected to exceed *ca.* 1 ppm (i.e. 1 mg/ liter).

In larger operations, it is anticipated that the spray treatment will be applied to the meat chunks as they pass through a semi-enclosed, baffled spray cabinet. The spray will be applied via pressurized spray nozzles, for up to about 30 seconds before the carcass exits the cabinet. The semi-enclosed spray cabinet area will be negatively pressurized via an aspirating air hose venting into a drain pipe located in the base of the cabinet. This will ensure the removal of excess fluid and gaseous materials. The drain pipe will be routed to an enclosed drain for removal with other wastes.

While chlorine dioxide has a minimum tendency to form when chlorite and acid are initially combined immediately prior to spraying, it has an increasing tendency to form as the solution concentrates during the evaporative process. Thus, in a typical situation, the potential for chlorine dioxide entry into the air of the workplace would be expected to derive from both that initially formed in solution (estimated as < 1.0 ppm), and any formed during evaporation. Chlorine dioxide also has a significant tendency to react with, and be degraded by soluble organic matter (such as blood proteins) to chlorite and ultimately chloride. It is

Revised: October 8, 1999



therefore expected that a major portion of both the initially projected chlorine dioxide maximum of 1 mg/liter of solution and any quantity formed upon subsequent solution evaporation will be reduced to a non-volatile, chlorine-containing ion that would be removed in the water.

It is further expected that the degree of ASC evaporation of, and concentration-induced creation of chlorine dioxide during the treatment's 30-second residence time on the meat pieces will be low. This is particularly true because the high humidity conditions prevailing in the cabinet will tend to suppress evaporation. Thus the projected 1 mg/liter level of chlorine dioxide is expected to correspond to the maximum amount from both initial and evaporative sources.

To put this into perspective, assume that an ASC spray operation uses 5 ml of ASC solution per pound of meat, of which about half that amount is retained on the product. For every 1,000 pounds of meat, the corresponding 5 liters of solution that would be used might release up to 5 mg of chlorine dioxide, at the 1 ppm maximum projected loss. Assuming a static air environment, with no venting or circulation of the air in the vicinity of that quantity of meat, the dispersal of 5 mg into only 17 M<sup>3</sup> of air would bring its concentration to the OSHA 8-hour TLV of 0.3 mg/M. It is fully expected that with venting and circulation of the air associated with a throughput of 1,000 pounds of meat, that the maximum projected chlorine dioxide air level would therefore not be a safety concern. A dipping operation, with less air dispersal of the ASC than a spray operation, would provide even less chlorine dioxide to the surrounding air.

## 6.2 USE RELEASES

The Environmental Assessment Section (H) of Alcide Corp.'s FAP 7A4532, which successfully sought the safe use of antimicrobial ASC solutions in the processing of red meat carcasses, contained a good deal of relevant information on the subsequent use of ASC solutions on subprimal and secondary meat cuts, and related specialty meat products. Of particular importance is the fact that about 50% of the US red meat consumption is in the form of ground product, such as hamburger, ground beef and sausage. Thus the information provided to substantiate the environmental safety associated with ASC solution use in the post-slaughter processing of meat carcasses is directly applicable to the subsequent use of these same solutions on 50% of the quantities of meat that were initial candidates for such use. Alcide believes that no extraordinary circumstances will exist at any of the sites of production or use of the subject additive, Acidified Sodium Chlorite, that will create situations inconsistent with the projected environmental releases and emission compliances.

The key areas of potential concern are as follows:

### 6.2.1 WATER AND AIR RELEASES

The components of the ASC solutions are the GRAS acid, of high purity, and the sodium chlorite (of a technical grade) which has sodium chloride and sodium chlorate as impurities. Upon acidification the chlorite, through chlorous acid, will slightly transform to chlorine dioxide and chlorate. At the level of use of these components, and the minimum standing time for the mixed ASC solution, the amount of chlorine dioxide will not exceed *ca.* 1 ppm. And, being a highly reactive compound, will be quickly reduced by reaction with organic matter and microorganisms on the meat pieces. The reduction will be to even smaller quantities of chlorite and chloride ions, with an even lower amount of chlorate being formed by a disproportionation of the chlorine dioxide.

The air releases of chlorine dioxide, as shown in the previous Section 6.1. and as more fully considered in the previous FAP 7A4532, are considered to be negligible. Of greater possible concern are the relatively higher levels of sodium chlorite, i.e. 1200 ppm as a maximum, of which the chlorite ion represents 895 ppm. For larger processing facilities, the information that was provided in the earlier FAP for the post-slaughter spraying of meat carcasses is directly applicable to the larger facilities where spray application of the ASC to subprimal and secondary cuts will be carried out. Since <50% of US ground meat will be prepared in large facilities, the environmental safety that was shown to be associated with the treatment of red meat carcasses will be similar to such use in down-the-line facilities. The area of potential concern not covered by the initial FAP is that relating to smaller volume use of ASC solutions such as in supermarkets, small sausage-making operations and local butcher shops.

#### **6.2.1.a Water releases - Smaller facilities**

It is anticipated that most of the ground meat in the US, perhaps ~30%, will be produced in the larger facilities (e.g., Iowa Beef Packers and contract patty makers) which provide hamburger patties for such major consumer outlets as McDonalds, Burger King and Wendy's. The remaining ASC usage will be distributed over a wide range of local facilities, thereby reducing the per site ASC volume. The actual volume of ASC solution that will be used in the smaller grinding operations, irrespective of whether it is applied by dip or spray, will reasonably represent a smaller fraction of the total water used by that facility than would apply in the large-scale, high-volume spray operations covered in FAP 7A4532.

Because of the diversity of such small-use operations the prediction of specific ASC quantities with respect to other waters in the effluent of a particular type of facility does not seem feasible. However it can be readily concluded that the much smaller chlorite quantities in the facility's effluent would be at least as

likely to react with and be degraded by the organic matter in its effluent water as for the larger facilities'. For the latter, reference to Section 6.2.1. of FAP 7A4532 will show that the maximum level of oxychlorines (mostly chlorite) that might be expected in the plant effluent of a carcass operation is ~0.005 ppm.

With respect to the acids used to acidify the sodium chlorite to the petitioned pH range of 2.5 - 2.9, the following are representative levels of GRAS acids required to achieve that range (buffering included):

Sulfuric acid-	≤0.005% (≤50 ppm)
Phosphoric acid-	0.01 - 0.02% (100 - 200 ppm)
Malic acid-	0.02 - 0.04% (200 - 400 ppm)
Acetic acid-	1.5 - 2.5%

These levels are quite low, and will be significantly diluted further by other water sources contributing to the facilities' effluents. They are therefore of little environmental concern. Even the specified range of acetic acid, which has been approved by FSIS at that level for carcass disinfection, is projected to yield diluted effluents above at least 5.5 pH.

#### **6.2.1.b Air releases - Smaller facilities**

As seen earlier, the spray application of the ASC solution to the meat pieces would create negligible air levels of chlorine dioxide, in an environment of normal air turnover, even without the use of a spray cabinet to confine its dispersal. In a small ASC dip operation, where meat pieces will generally have some liquid exudate on their surfaces (in which soluble proteins will be contained) this organic matter has been seen to destroy any small levels of chlorine dioxide that may have formed in the solution upon its activation. In experiments in which pieces of meat have been immersed in ASC dips solutions, there has been no noticeable odor of chlorine dioxide above these solutions. The odor threshold for chlorine dioxide detectability is  $\sim 0.1 \text{ ppm}^2$ . The OSHA TLV for chlorine dioxide is also 0.1 ppm, for continuous 8-hour exposure<sup>3</sup>. Thus it does not appear that the dipped application of ASC solutions to meat cuts will bring about unsafe air levels of chlorine dioxide in the environment of the dip operation.

#### **6.2.2. RELATION OF PLANT WATER RELEASES TO TOTAL PUBLICLY OWNED TREATMENT WORKS QUANTITIES**

The industrial discharges, such as from plants which process subprimal and secondary meats, to local Publicly Owned Treatment Works (POTWs) are further diluted by discharges from other industrial as well as from non-industrial sources. Alcide's Environmental Assessment Document (Section H of FAP 7A4532) that was part of its petition for use of ASC solutions in carcass processing, discussed the relationship of such plant discharges to total POTW intakes. Reference was made to an EPA-sponsored study<sup>4</sup> which provided guidance in minimizing the discharge effects on these POTWs. In that report it was shown that the average influent waste water from industrial sources was 26.3% of the total intake. That information was used to estimate the projected impact of the meat-processing facilities using ASC treatments.

Since  $\sim 50\%$  of the red meat used in this country is consumed as a ground product,

it can be presumed that none of the various facilities which will be using the petitioned ASC solutions will approach the volume usage characteristic of the various primary carcass processors. Thus the subsequent dilution of effluents from down-the-line meat processors can be expected to result in lower oxychlorine discharges to the POTWs than from those from the carcass processors. If, as calculated in FAP 74532, the contribution from a carcass processor to its handling POTW is a maximum 12 parts per billion (ppb), the contribution from a down-the-line processor should be less than that. A similar analogy holds for the food-grade acids used for ASC activation, where the acid contribution to POTW facilities would be *de minimus*.

On the basis of these discussions, and the background in Section H of the previous petition, FAP 7A4532, the Alcide corporation does not believe that the above-indicated concentrations of oxychlorine species or food acids will have a negative impact on the operation of POTW, for the following reasons:

- a) The levels of oxychlorines, *i.e.*, chlorite, chlorate, and chlorine dioxide, that would reach the POTW's, is at the ppb level, at most. Neither chlorite, chlorate nor chlorine dioxide is listed as an Interfering Substance in POTWs, as provided in a document listing Interferences at POTWs<sup>5</sup>. These interfering substances, as contained in certain industrial discharges, can cause "a POTW's noncompliance with its permit or inability to lawfully use or dispose of its sludge." Acidity is also listed as a potential interference in POTW operation, but the levels contributed by this application would not have a measurable impact on pH.

- b) None of the species present at the levels indicated can interfere with the microbiological treatment systems. Chlorine dioxide, a recognized antimicrobial, will have no effect at the calculated ppb level; neither will the chlorite, a much weaker source of activity, at the minuscule levels possibly present.

### 6.2.3 COMPLIANCE WITH EMISSION REQUIREMENTS

Alcide is not aware of any federal, state or local water or air emission regulations applicable to chlorite, chlorate or chlorine dioxide. Alcide fully anticipates that any red meat grinding operation that intends to use the acidified sodium chlorite solutions, if deemed appropriate, will obtain the necessary permits and approvals for discharging process waters containing chlorite, chlorate and chlorine dioxide to POTWs. It should be noted that sodium chlorite, used in preparation of these ASC solutions, is an EPA-registered product. It is Alcide's current intention to use one of three EPA registered sodium chlorite products for the proposed application (or the equivalent): Vulcan Chemicals' 79% Technical Sodium Chlorite, Technical Sodium Chlorite Solution 31.25, and 31% Active Sodium Chlorite Solution. Copies of the Technical Data Sheets and Material Safety Data Sheets for these products are provided in Appendix I of this section. Alcide intends to request that Vulcan Chemicals include label copy which mandates that users of the sodium chlorite must discharge the solutions in accordance with the requirements of the facility's National Pollution Discharge Elimination System permit. Any warning statements on the labels concerning the hazard of the products to organisms that may be exposed to it in the environment will also be on the labels of the FDA-regulated use.

### 6.2.4 COMPLIANCE STATUS

Sodium chlorite has a number of commercial uses, primarily as a source of chlorine dioxide, *e.g.*, pulp and paper bleaching, drinking water treatment, as a slimeicide in cooling towers, as a food disinfectant, and as a cleaning agent in the electronics industry.

The current U.S. production of sodium chlorite is close to 25 million pounds. The 1994 slaughter data for animals in federally-inspected plants, according to the American Meat Institute, was:

Cattle-	32,593,000
Veal/Calves-	1,159,000
Hogs-	90,000,000
Sheep & Lambs-	5,001,000

If 50% of the meat from all of these animals were to be treated, most of which being converted to ground meat, and using the maximum petitioned 1200 ppm ASC solution, the amount of sodium chlorite employed would certainly not exceed the amount which had been calculated, in the original FAP 7A4532, for the treatment of all of these animals post-slaughter. That amount, approximated as 50,765 pounds annually, was shown to be ~0.2% of the total sodium chlorite consumed annually in this country. So total ASC treatment of all animals post-slaughter combined with its complete usage on all meat cuts intended for grinding would still represent a small percentage of total sodium chlorite use for meat processing.

To take that calculation one step further, one may consider that ASC solutions are also federally approved for use in poultry processing waters. In the corresponding Environmental Assessment (Section H of FAP 4A4433) it was computed that complete use of the ASC's on all the 7.0 billion chickens processed per year would correspond to a sodium chlorite usage that would be 2% of current annual consumption. This use-volume, of course, is an over-exaggeration. So application of the ASC antimicrobial solutions, in realistic terms, would probably not exceed ~1% of current sodium chlorite usage when the treatment is applied in poultry processing as well as both initial and secondary stages of red-meat processing.



## **7.0 FATE OF EMITTED SUBSTANCES IN THE ENVIRONMENT**

Sodium chlorite, sodium chlorate and chlorine dioxide released into the environment will likely undergo reduction in contact with organic matter, and/or microbial degradation wherein microorganisms can use the oxychlorines as an oxygen source when present at sublethal levels. Ultimately the oxychlorines will be reduced to the chloride ion,  $\text{Cl}^-$ .

## 8.0 ENVIRONMENTAL EFFECTS OF RELEASED SUBSTANCES

### 8.1 EFFECTS ON AQUATIC ORGANISMS

Summaries of relevant portions of this section, as presented in FAP 7A4532 for the oxychlorines that might enter the environment as a result of meat carcass treatment are provided in the next paragraphs. Following the discussion of each specific oxychlorine is a projection of effects from each of these materials as a result of pre-treatment of meat cuts prior to grinding.

Sodium Chlorite: The  $LC_{50}$  aquatic toxicity to fish and oyster species ranged from 41 to 149 ppm, and from 151 to 650 ppb for *Daphnia magna* and Mysid shrimp, resp. The EPA has determined that sodium chlorite is toxic to fish, on the basis of the *Daphnia magna* figure. It was shown in Section 6.2.1.a. that a maximum level of about 5 ppb of sodium chlorite would reach the typical POTW, which amount is much below a level of concern. And further, during subsequent wastewater treatment processing, there is a potential for further dilution of those projected minimum levels of emission. For effluents that might not be directed to POTWs, but are directed to catch ponds and leaching beds, the high levels of organic matter in the earth environment would rapidly reduce the chlorite to safe levels before the entraining water reached habitable waters for aquatic species.

Sodium Chlorate: The  $LC_{50}$  for freshwater and marine fish is consistently >1000 ppm. Sodium chlorate, being a small fraction of the impurities in technical grade sodium chlorite, and forming to only a minor extent during the degradation of ASC solutions, is therefore of no concern from their use in carcass treatments. This conclusion is also directly applicable to the lower volume use of ASC's for prior treatment of meat cuts intended for grinding.

**Chlorine Dioxide:** The rapidity of degradation of chlorine dioxide in organic environments, coupled with its minimum production in ASC solutions eliminates any aquatic toxicity concerns from carcass treatments. This conclusion is also appropriate for effluents resulting from ASC use on meat cuts prior to their comminution.

## **8.2. EFFECTS ON TERRESTRIAL ORGANISMS**

A summary of the corresponding section in the prior FAP, 7A4532, for red meat carcass processing, is provided in the following paragraphs. Included in that summary are comments with respect to anticipated toxicity's resulting from use on pre-ground meat cuts.

A broad variety of toxicological studies have been carried out on the oxychlorine species chlorite, chlorate and chlorine dioxide, in connection with the worldwide use of chlorine dioxide in the disinfection of potable water. The  $\text{ClO}_2$  has been found to produce virtually no chlorinated hydrocarbons as potential mutagens, as does chlorine. On a concentrated basis, the oxychlorines have been found to cause oxidative changes to erythrocytes, both in loss of structural integrity and formation of methemoglobin. However at the ppb levels where these materials may be found in red meat processing plant effluents, be they primary or subprimal and secondary meat grinding operations, the data obtained in connection with drinking water levels of the oxychlorines are more relevant.

On an acute basis, the toxicity of sodium chlorite is in the range of 300 - 350 mg/kg, based on the  $\text{LD}_{50}$  values for mice, rats, and guinea pigs. For sodium chlorate, the  $\text{LD}_{50}$ 's cover the range of ~600 to 8000 for mice, rats, dogs, cats and rabbits. With respect to the acute toxicity of chlorine dioxide, an  $\text{LD}_{10}$  of 500 ppm was found for 15 minutes air exposure by rats. In man, a 5 ppm level in the air was found to be an irritant to the respiratory and G.I. tracts. Such levels would not be found in meat processing plants, either carcass or grinding operations, where any sub-ppm levels of  $\text{ClO}_2$  formed during production of the ASC solutions would be rapidly destroyed by organic matter on the carcass or the meat pieces.

A variety of sub-acute studies have been conducted on animals and human volunteers, who ingested waters containing up to 40 ppm of chlorine dioxide in a single episode, or 5 ppm solutions of chlorine dioxide or sodium chlorite for a 12 week period. In the latter case there were some effects on blood chemistry, but little other effects. In the former case there was headache, nausea and abdominal discomfort which passed in 5 minutes.

A recently completed rodent 90-day study, considered to be the "most definitive and comprehensive study of chlorite undertaken" and ....considered....the most relevant basis for risk assessment"<sup>6</sup> was used, in conjunction with the earlier studies to calculate a NOEL (no observed effect level) of 5/mg/kg/day for chlorite in drinking water. This corresponds to 350 mg/kg/day intake for a 70 kg individual. Applying a 100-fold safety factor, this reduces to a recommended maximum intake of 3.5 mg/day for that individual. In the same publication a NOEL for chlorate is recommended of 78 mg/kg/day, which translates to a maximum intake of 54.6 mg of chlorate per day for a 70 kg person, including the 100 fold safety factor. For chlorine dioxide, the NOEL of 3.5 mg/kg/day is recommended, translating to an intake of 2.45 mg/kg/day for the 70 kg individual.

On the basis of the oxidative tendency of these oxychlorine species to be chemically reduced by organic matter in both the meat treatment, post-washing and plant sanitation waters, and subsequent municipal water treatment facilities, the levels of the three oxychlorine species are anticipated to be significantly lower than the levels calculated to be of minimal risk to individuals.

### **8.3 ENVIRONMENTAL BENEFITS**

The use of acidified sodium chlorite acid systems for treatment of meat- and specialty- meat cuts offers the possibility of several environmental benefits:

### 8.3.1 NON-FORMATION OF MUTAGENS AND CARCINOGENS

In those instances where ASC solutions might be used, or are used in place of chlorinated water for disinfecting meat surfaces (not a common practice), the potential for the formation of chlorinated organic materials in the environment would be significantly reduced.

### 8.3.2. REDUCTION IN AQUATIC TOXICITY

Similar considerations would apply to the reduction of hypochlorite in aquatic environments, which has the following toxicity<sup>7</sup>

- Cold water fish: 0.132 - 135 ppm (LC<sub>50</sub>-96 hr)
- Warm water fish: 0.28 - 2.1 ppm (LC<sub>50</sub>-96 hr)
- *Daphnia magna*: 0.037 - 2.1 ppm (LC<sub>50</sub>-48 hr)

These data indicate that chlorine/hypochlorite is much more toxic to both cold and warm freshwater fish than is chlorite or chlorate, and generally slightly more toxic to the *Daphnia magna* invertebrate.

## **9.0 USE OF RESOURCES AND ENERGY**

As shown earlier in format section 6, if all of the secondary meat cuts, organs, and related products in the United States were to be first treated with ASC solutions, and such solutions were similarly used on all red meat carcasses and all the chickens processed annually in the US, the amount of additional sodium chlorite consumed would only be ~2.3% of the total present consumption of sodium chlorite. Inasmuch as the eventual use of ASC solutions in these multiple applications will obviously be significantly less than that maximum, the impact on national resources and energy by such incremental use will be insignificant. Also no minerals will be used in the preparation or production of the subject additive. Environmental releases of chlorite, chlorate, chlorine dioxide and any of the GRAS acid activators are not expected to adversely affect threatened or endangered species nor impact historic structures.

Revised: October 8, 1999

F:\R&D\700 REGULATORY\754 BEEFANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)environmental assessment-amendment 001.doc Page 28 of 34

**A-00028**

## **10.0 MITIGATION MEASURES**

No adverse environmental effects are anticipated from residual "worst-case" levels of chlorine dioxide as a result of any aspect of use of the subject additive, if this petition is approved. Therefore, no mitigation measures are required.

**Revised: October 8, 1999**

## **11.0 ALTERNATIVES TO PROPOSED ACTION**

Inasmuch as no potential adverse environmental effects are expected to occur, no mitigation alternative actions are necessary.

**Revised: October 8, 1999**

FAR&D\700 REGULATORY\754 BEEF\ANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)\environmental assessment-amendment 001.doc Page 30 of 34

**A-00030**



## **12.0 PREPARER**

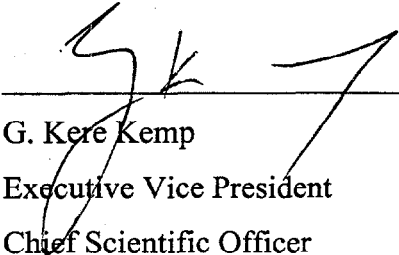
This Environmental Assessment was prepared by Robert D. Kross, Ph.D. of Kross-Link Laboratories. Dr. Kross has an educational background in physical chemistry, analytical chemistry and physics, and has consulted in the fields of oxychlorine chemistry, food & nutrition, biochemistry, microbiology, toxicology and environmental analysis. He was an intervenor in the siting of the Shoreham Nuclear Power Plant of the Long Island Lighting Corporation.

**Revised: October 8, 1999**

## 13.0 CERTIFICATION

The undersigned official certifies that the information presented is true, accurate and complete to the best knowledge of the firm.

Date: October 8, 1999

Signature:   
Name: G. Kere Kemp  
Title: Executive Vice President  
Chief Scientific Officer

Revised: October 8, 1999

## **14.0 APPENDICES**

**Appendix 1. Sodium Chlorite Technical Data Sheets and Materials Safety Data Sheets.**

**Revised: October 8, 1999**

F:\R&D\700 REGULATORY\754 BEEFANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)\environmental assessment-amendment 001.doc Page 33 of 34

**A-00033**

## 15.0 BIBLIOGRAPHY

---

1. Private communication from the American Meat Institute.
2. Household Odors Associated with the Use of Chlorine Dioxide during Drinking Water Treatment; Hoehn, RC, RG Lee, EM Aleta and DW Wood, Presentation to the Annual AWWA Conference and Exposition, "Identification and Treatment of Taste and Odor Compounds, Los Angeles, CA, June 18, 1989.
3. American Conference of Governmental Industrial Hygienists Inc. Cincinnati, Ohio 1986.
4. "Guidance Manual for Preventing Interference at POTWs," USEPA, Sept., 1987, NTIS Report No. PB92-117969.
5. Wetzel, ED and SB Murphy "Interferences at Publicly Owned Treatment Works," NTIS Report No. PB90-108853.
6. CHLORINE DIOXIDE-DRINKING WATER ISSUES; Second International Symposium, May 7,8, 1992, Chemical Manufacturers Association/American Water Works Association-Research Foundation/ United States Environmental Protection Agency, pages 177-181.
7. Reregistration Eligibility Document for Sodium and Calcium Hypochlorite Salts, February 1992. NTIS Report No. 540/RD-92-193.

Revised: October 8, 1999

F:\R&D\700 REGULATORY\754 BEEF\ANTIMICROBIAL\754B-FDA-FAP\Beef Parts Food Additive Petition Files\171.1(c)(H)environmental assessment-amendment 001.doc Page 34 of 34

A-00034

**PRODUCT SPECIFICATION****Sodium Chlorite****(NaClO<sub>2</sub>)****Technical Sodium Chlorite Solution 31.25**  
**(25% Active Sodium Chlorite)****COMPONENT****SPECIFICATIONS**

Sodium Chlorite, wt% as NaClO <sub>2</sub>	24.25 - 25.75
Sodium Chlorate, wt% as NaClO <sub>3</sub>	0.7 max.
Sodium Chloride, wt% as NaCl	3.0 max.
Total Alkalinity, wt% as NaOH @ pH4	0.5 max.
Hydrogen Peroxide, wt% as H <sub>2</sub> O <sub>2</sub>	0.01 max.
Water (by difference), wt%	70 - 75

**TYPICAL PROPERTIES**

Appearance	Clear, slightly yellow liquid
Turbidity, NTU	10 max
Density, lb/gal @ 25°C	10.1 (typical)

Typical properties are listed for information only, and are not to be considered as specification requirements. These items are not analyzed on a routine basis. Product meeting the specification test items will exhibit the listed typical properties.

**CONTAINERS:**

Tank Trucks (stainless steel) - 3400 gallon  
Drums - 55 Gallon Plastic Drums, 565 lbs net  
VMC non-returnable 275 gallon tote with steel box and plastic bottle  
Customer provided returnable totes

NSF Listed, ANSI/NSF Standard 60 (Wichita, KS)  
Meets requirements of AWWA B303-88  
EPA Reg. No: 5382-43

**A-00035**



## SODIUM CHLORITE (Powder)

### SPECIFICATIONS

REF. 12P/IN REV.Nº2 MAY,96

EC Nº N/A  
IMO CODE 1.498

EINECS 23 18 366  
CAS 7758.19.2

	GRADES		
	PS	PN	
Sodium Chlorite ( $\text{NaClO}_2$ ) wt %	80 +/- 1	80 +/- 1	
Total alkalinity ( $\text{NaOH}$ ) wt %	1	1	MIN.

#### TYPICAL VALUES

Sodium Chlorate ( $\text{NaClO}_3$ ) wt%	1	1
Sodium Chloride ( $\text{NaCl}$ ) wt%	7-9	2
Sodium Carbonate ( $\text{Na}_2\text{CO}_3$ ) wt%	5-8	3
Sodium Hydroxide ( $\text{NaOH}$ ) wt%	1	1
Sodium Nitrate ( $\text{NaNO}_3$ ) wt%	-	14-16
Sodium Sulphate ( $\text{Na}_2\text{SO}_4$ ) wt %	3-5	-

Hazard in transportation-storage handling:

See our Safety Data Sheet ref. S MA 09.05.90

Standard Packing:

Metal drums of 50 and 100 Kg on pallets upon request.

Aragonesas has undertaken the COMPROMISO DE PROGRESO, the Spanish equivalent to RESPONSIBLE CARE

All its production sites are certified by AENOR to comply with ISO 9002.

A-00036



A Division of  
Vulcan Materials Company

P.O. BOX 530390  
Birmingham, AL 35253-0390  
(205)877-3000

## TECHNICAL DATA SHEET

Code No.: 6-1-0

### SODIUM CHLORITE ( $\text{NaClO}_2$ )

Technical Sodium Chlorite  
(79% Min. Active Sodium Chlorite)

### SPECIFICATIONS

#### COMPONENT

#### SPECIFICATIONS

Sodium Chlorite, wt% as $\text{NaClO}_2$	79 - 85
Sodium Chlorate, wt% as $\text{NaClO}_3$	4 max.
Sodium Chloride, wt% as $\text{NaCl}$	9 - 17
Sodium Hydroxide, wt% as $\text{NaOH}$	3 max.
Sodium Carbonate, wt% as $\text{Na}_2\text{CO}_3$	2 max.
Sodium Sulfate, wt% as $\text{Na}_2\text{SO}_4$	3 max.
Hydrogen Peroxide, wt% as $\text{H}_2\text{O}_2$	.01 max.
Water (by difference), wt%	6 max.
Arsenic, ppm	3 max.
Lead, ppm	10 max.
Heavy Metals as Pb, ppm	30 max.
Mercury, ppm	0.1 max.

#### CONTAINERS:

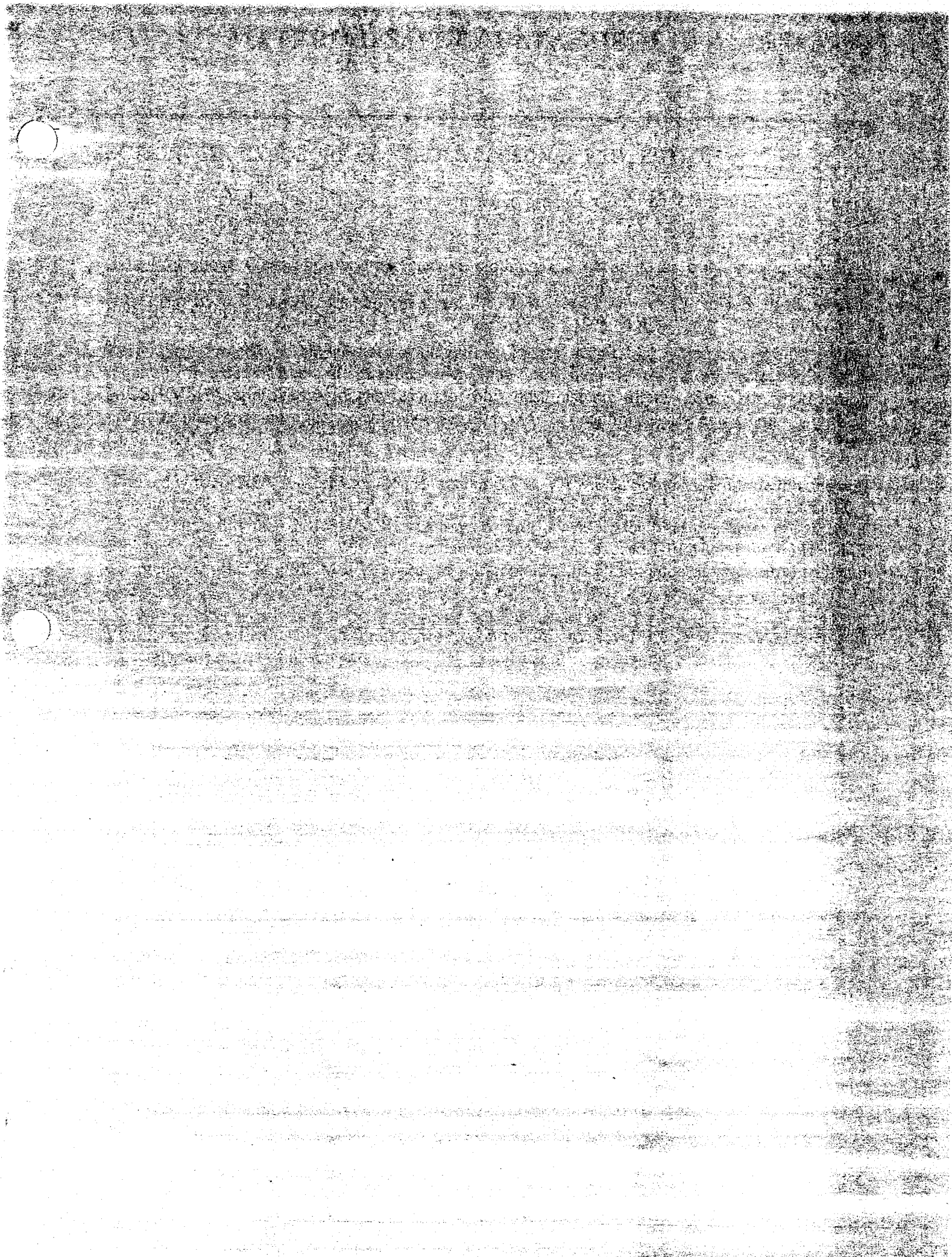
Drums - 100 pounds net

NSF listed, ANSI/NSF Standard 60

Meets requirements of AWWA B303-88

EPA Reg. No: 5382-42

A-00037





# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 1 of 8

**ALCIDE CORPORATION**  
**8561 154th Avenue NE**  
**Redmond, WA 98052**

**Telephone: 1-(425) 882-2555**  
**For Emergencies: 1-800-424-9300**  
**(Chemtrec)**

## **SANOVA® BASE CONCENTRATE**

### **SECTION I. PRODUCT IDENTIFICATION**

**Synonyms:** Sodium Chlorite Solution  
**Chemical Formula:** Mixture of H<sub>2</sub>O, NaClO<sub>2</sub> and NaOH  
**Product Description:** Mixture of water, sodium chlorite and sodium hydroxide  
**Product Use:** Component of aqueous antimicrobial solution for food processing

### **SECTION II. COMPOSITION/INFORMATION ON INGREDIENTS**

<u>Chemical Ingredients</u>	<u>Reg. CAS No.</u>	<u>% by weight</u>
Water	7732-18-5	70 - 75%
Sodium Chlorite	7758-19-2	21.7 - 24.0%
Sodium Hydroxide	1310-73-2	4.0 - 4.5%

<u>Exposure Limits</u>	<u>OSHA PEL</u>	<u>1997 ACGIH TLV</u>
Sodium chlorite (8 hr TWA)	None Established	None established
(15 min STEL)	None established	None established

Note: PEL - Permissible Exposure Limit      TLV - Threshold Limit Value  
TWA - Time Weighted Average      STEL - Short Term Exposure Limit

### **SECTION III. HAZARDS IDENTIFICATION**

**DANGER! DO NOT CONTACT WITH SANOVA ACTIVATOR  
CONCENTRATE OR SANOVA MIXED SOLUTION.  
THIS WILL PRODUCE CHLORINE DIOXIDE. SEE  
SECTIONS VIII AND X.**

#### Emergency Overview

Clear, colorless to slightly yellow liquid, with slight bleach-like odor.  
Contains sodium chlorite.

**DANGER! CAUSES EYE AND SKIN BURNS**

**MAY CAUSE RESPIRATORY IRRITATION**

**HARMFUL IF INHALED OR SWALLOWED**

MSDS  
SANBAS  
REV. 04

**A-00038**

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 2 of 8

---

## SECTION III. HAZARDS IDENTIFICATION (cont'd)

### Preventative Measures

Do not get in eyes, on skin or clothing. Avoid breathing mist or fumes. Use with adequate ventilation. Keep container closed. Wash thoroughly after handling. This product becomes a fire or explosive hazard if allowed to dry. Wash contaminated clothing to minimize fire hazard. When this base concentrate has been diluted, it becomes less hazardous.

### Potential Health Effects

*Eye Contact:* Splashes and mists may cause severe irritation and possible burns. Symptoms include tearing, redness and in severe cases, eye damage due to burns.

*Skin Contact:* May cause severe irritation and possible burns. Symptoms include redness, itching, swelling and possible destruction of tissue.

*Inhalation:* May cause irritation of the respiratory system. Symptoms may include labored breathing, coughing, sore throat and sneezing.

*Ingestion:* May cause irritation to the gastrointestinal tract. Symptoms may include nausea, vomiting, sore throat, abdominal pain and diarrhea. Swallowing large amounts may cause cyanosis and anemia due to oxidizing nature of sodium chlorite.

*Chronic Effects:* No information was found for sodium chlorite on the long term effects of breathing mists/fumes and skin contact. Sodium chlorite is toxic by ingestion. Refer to Section XI for details.

*Aggravation of Pre-existing Health Problems:* Respiratory and blood diseases.

*Note to Attending Physician:* Chlorine dioxide vapors are emitted when this product contacts acids or chlorine. If these vapors are inhaled, monitor patient closely for delayed development of pulmonary edema which may occur up to 48-72 hours post inhalation.

Following ingestion, neutralization and use of activated charcoal is not indicated.

---

## SECTION IV. FIRST AID PROCEDURES

*IF IN EYES:* Immediately flush eyes with plenty of water for at least 15 minutes, lifting upper and lower eyelids occasionally. Get immediate medical attention.

*IF ON SKIN:* Immediately flush skin with plenty of water for at least 15 minutes. Remove contaminated clothing and shoes. Wash clothing and clean shoes before reuse. Get medical attention if irritation or burning persists.

*IF INHALED:* Remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. Get immediate medical attention.

MSDS  
SANBAS  
REV. 04

A-00039

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 3 of 8

**IF SWALLOWED:** Do not induce vomiting. Give large quantities of water. Never give anything by mouth to an unconscious person. Get immediate medical attention.

---

## SECTION V. FIRE FIGHTING MEASURES

**Fire Fighting Instructions:** In the event of a fire, wear full protective clothing and self-contained breathing apparatus with full-face piece (pressure demand, MSHA/NIOSH approved). Approach any fire from upwind to avoid hazardous vapors and toxic decomposition products. Equipment should be thoroughly decontaminated after use.

**Flammable Properties:** SANOVA Base is not combustible. However, it may become a fire or explosion hazard if allowed to dry.

**Extinguishing Media:** Use water spray to keep fire-exposed containers cool and to prevent drying. Do not use dry chemical, CO<sub>2</sub> or Halon extinguishers. Use media suitable for surrounding fire. Dike and collect water used to fight fire as runoff may cause environmental damage.

---

## SECTION VI. ACCIDENTAL RELEASE MEASURES

**Spills:** Remove ignition sources. Ventilate spill area. Observe all hazards noted in Section III; especially avoiding mixing of the SANOVA Base Concentrate with SANOVA Activator Concentrate or SANOVA Mixed Solution. Wear personal protective equipment as specified in Section VIII. Evacuate all non-essential personnel in the area and downwind. Keep any spill from drying out by adding water. Sodium chlorite can produce explosive chlorine dioxide gas if it contacts acids, such as SANOVA Activator Concentrate, SANOVA Mixed Solution, or chlorine. Stop spill as soon as possible and alert appropriate personnel. Water fog or spray can suppress vapors. Dike runoff to sewers and waterways. Absorb spilled material with clay, soil or non-flammable commercial absorbents. Continue to keep residue damp. Containerize and label all spilled material. Dried material can ignite combustible materials. Wash all contaminated clothing and wash spill area with detergent and rinse with water if permitted.

---

## SECTION VII. HANDLING AND STORAGE

**Handling:** Do not get in eyes, on skin or clothing. Avoid breathing mist and fumes. Use with adequate ventilation. Use protective equipment mentioned in Section VIII. Keep container closed and upright. Do not drop, roll or skid drum. Follow all MSDS and label precautions until container is cleaned, reconditioned or destroyed as container may retain vapor and product residues. Wash thoroughly after handling.

**Storage:** Keep in a tightly closed container. Containers must not contain combustible or readily oxidizable materials or sulfur-containing rubber. Keep away from heat, flames and sources of ignition. Do not store at temperatures above 100° C (212° F) or in direct sunlight or ultraviolet light. Store in a cool, dry, ventilated area under sanitary conditions with other food grade ingredients. Keep container closed when not in use. Protect from physical damage. Keep from freezing.

MSDS  
SANBAS  
REV. 04

A-00040

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 4 of 8

---

## SECTION VIII. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Eye Protection:** Wear chemical safety goggles or a face shield when performing operations with the potential for splash. Facilities storing or using this product should have an available eye wash facility and safety shower.

**Skin Protection:** Wear appropriate protective clothing and neoprene or butyl rubber gloves to prevent skin contact. Wash thoroughly after handling. Personal protective equipment programs must be in compliance with 29 CFR 1910.132.

**Respiratory Protection:** Under normal conditions of use, respiratory protection should not be required. In emergencies and situations where monitoring indicate respiratory protection, wear a NIOSH/MSHA approved acid gas respirator plus dust/mist pre-filters. Respiratory protection programs must be in compliance with 29 CFR 1910.134. For confined space entry, comply with 29 CFR 1910.146.

If mixed with SANOVA Activator Concentrate or SANOVA Mixed Solution, chlorine dioxide will be generated. Where vapor concentrations of chlorine dioxide exceed or are likely to exceed 0.1 PPM, wear a full face NIOSH/MSHA approved acid gas respirator plus dust/mist pre-filters if exposure to mist is possible. Where vapor concentrations may exceed 1 PPM and for spills and/or emergencies, wear NIOSH/MSHA approved self-contained breathing apparatus (SCBA) with full face-piece.

**Ventilation:** Local exhaust is recommended to control airborne levels of vapors, mists or aerosols especially at sources of air contamination such as open containers and process vessels. Otherwise, use general exhaust ventilation.

---

## SECTION IX. PHYSICAL AND CHEMICAL PROPERTIES

**Appearance:** Clear, colorless to slightly yellow liquid with slight bleach-like odor.

**Solubility in Water:** Completely soluble

**Specific Gravity @ 25°C (77°F):** 1.24

**pH @ 25°C (77°F):** 12-13

**Decomposition Temperature (dry material):** 175°C (347°)

**Freezing Point:** Protect from exposure to temperatures below 0°C (32°F).

---

## SECTION X. STABILITY AND REACTIVITY

**Stability:** Stable under expected and reasonable conditions of storage and use.

**Reactivity:** Oxidizer.

**Incompatibilities:** Acids, including SANOVA Activator Concentrate and SANOVA Mixed Solution; reducing agents, combustible materials, sulfur containing materials, zinc, aluminum, hypochlorites (including bleach) and peroxides. Toxic chlorine dioxide gas will be generated on contact with acids, including SANOVA Activator Concentrate and SANOVA Mixed Solution; chlorine, hypochlorites (including bleach) or peroxides.

MSDS  
SANBAS  
REV. 04

A-00041

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 5 of 8

---

## SECTION X. STABILITY AND REACTIVITY (cont'd)

Hazardous Decomposition Products: Heating to decomposition will produce oxygen and highly toxic fumes of chlorine and sodium oxide.

Hazardous Polymerization: Will not occur.

Conditions to Avoid: Temperatures above 175° C (347° F), flames and ignition sources. Evaporation to dryness can cause ignition with combustibles. Sunlight and ultraviolet light can reduce product strength. In cases of contamination with incompatibles or decomposition, do not reseal container. Isolate container in an open and well-ventilated area and flood with large amounts of water.

---

## SECTION XI. TOXICOLOGICAL INFORMATION

Animal toxicology based on anhydrous sodium chlorite

Inhalation LC<sub>50</sub>

No information found

Dermal LD<sub>50</sub>

>2g/kg (rabbit)

Oral LD<sub>50</sub>

~350 mg/kg (rat)

Irritation

Severe irritant with corrosive action to skin (rabbit)

Severe irritant to eyes (rabbit)

The chronic ingestion of low concentrations of sodium chlorite has been studied in laboratory animals. Concentrations in the drinking water of 100ppm and higher have been shown to cause mild anemia and a minor suppression of thyroid functions in laboratory animals. All effects were reversible after cessation of treatment.

Clinical studies of communities using sodium chlorite as a disinfectant found no adverse effects in the human population studied. However, other studies have suggested that those individuals deficient in enzyme (G6PD), utilized in hemoglobin synthesis, might be susceptible to the development of anemia if exposed repeatedly.

### Carcinogenicity

Sodium chlorite is not listed by NTP, IARC, OSHA, EPA, or any other authority as a carcinogen.

### Mutagenicity

Sodium chlorite has been evaluated for possible mutagenic effects in several laboratory tests. Sodium chlorite tested positive in the Ames Salmonella reverse mutation assay without metabolic activators and caused chromosomal aberrations in an in-vitro Chinese hamster fibroblast cell line without metabolic activators. Sodium chlorite also tested positive in the mouse micronucleus assay when administered intraperitoneally (directly into the body cavity), but was not mutagenic when administered orally. The significance of these test results for human health is unclear because the oxidizing effects of the chlorite or salting effects of sodium may significantly affect the ability of testing to accurately detect mutagens.

MSDS  
SANBAS  
REV. 04

A-00042

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 6 of 8

---

## SECTION XV. REGULATORY INFORMATION (cont'd)

### Reproductive Toxicity

Sodium chlorite has not been found to be teratogenic in studies in which animals have been exposed up to 100 PPM in the drinking water. Male rats repeatedly exposed to concentrations of 100 PPM or greater in the drinking water have shown slight effects on sperm motility. No effects were observed at 10 PPM and no effects were observed on fertility rate, histology of the male reproductive system or conception rate of animals exposed at 10 PPM or higher.

---

## SECTION XII. ECOLOGICAL INFORMATION

Sodium Chlorite is slightly toxic to fish and other aquatic organisms. For bluegill (*Lepomis macrochirus*), aquatic toxicity studies have shown a  $TL_{50}$  of 208 mg/L and  $LC_{50}$  values of 265-310 mg/L. Rainbow trout (*Salmo gairdneri*) have been tested and shown acute toxicity value of 50.6 mg/L ( $TL_{50}$ ) and 290 mg/L ( $LC_{50}$ ). Of the aquatic species tested, *Daphnia* have been the most sensitive species tested with an  $LC_{50}$  of 0.29 mg/L.

Sodium chlorite is acutely toxic to birds when administered by gavage. The acute oral  $LD_{50}$  in mallard ducks is 0.49 - 1.00 g/kg. In bobwhite quail, the  $LD_{50}$  is 0.66 g/kg. Sodium chlorite in the diet of birds was not acutely toxic. Eight-day dietary  $LC_{50}$  in mallard ducks and bobwhite quail were both greater than 10,000 PPM in the diet.

---

## SECTION XIII. DISPOSAL CONSIDERATIONS

Dispose of all contaminated product, soil, debris, sorbents and other spill clean-up materials in accordance with applicable federal, state or local procedures.

Contaminated materials, including contaminated or unwanted product may be classified as hazardous under the Federal Resource and Conservation Act (RCRA) and related state laws.

---

## SECTION XIV. TRANSPORT INFORMATION

The US Department of Transportation regulates SANOVA Base as a hazardous material.

### **DOT SHIPPING DESCRIPTION (49 CFR 172.101)**

Chlorite Solution, Hazard Class 8, UN1908, Packing Group II

### PLACARD REQUIRED

Corrosive, 1908, Class 8

### LABEL REQUIRED

Corrosive, Class 8

The applicable packaging sections in 49CFR are 173.202 and 173.242

# MATERIAL SAFETY DATA SHEET

Date: August 1999  
Page 7 of 8

---

## SECTION XV. REGULATORY INFORMATION

SARA Hazard Notification: Physical & Health Hazard Categories, 40 CFR Part 370.2:

- ☒ Immediate (acute): Effects occur rapidly and are of short duration.
- ☒ Delayed (chronic): Effects occur as a result of long term exposure and are of long duration.
- ☒ Fire hazard: Oxidizer.
- ☐ Reactive hazard:
- ☐ Sudden Release of Pressure:

Section 313 Toxic Chemical(s)

Not applicable

OSHA Hazard Communication Standard:

Hazardous under the criteria of the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Toxic Substances Control Act

Listed in the Toxic Substance Control Act (TSCA) Inventory.

US Food and Drug Administration Approval:

Acidified Sodium Chlorite Solution (SANOVA Mixed Solution) is approved by Food Additive Petition. (21 CFR 173.325)

NFPA Hazard Identification Label

Health - 2 (moderate hazard)  
Fire Hazard - 1 (slight hazard)  
Reactivity - 1 (slight hazard);  
Specific Hazard - OX (oxidizer)

State List Data

Sodium chlorite: Florida Toxic Substance; Massachusetts hazardous substance codes - 5;

---

## SECTION XVI. OTHER INFORMATION

MSDS Number: SANBAS REV. 04, 08/99

FOR EMERGENCIES CONTACT 1-800-424-9300 (Chemtrec)

FOR ADDITIONAL NON-EMERGENCY INFORMATION, CONTACT:

ALCIDE CORPORATION

TELEPHONE: 1 (425) 882-2555

FAX: 1 (425) 861-0173

MSDS  
SANBAS  
REV. 04

**A-00044**

# MATERIAL SAFETY DATA SHEET

Date: August 1999

Page 8 of 8

---

## SECTION XVI. OTHER INFORMATION (cont'd)

Although the information and recommendations set forth herein (hereinafter "Information") are presented in good faith and believed to be correct as of the date hereof Alcide Corporation makes no representations as to the completeness or accuracy thereof. Information is supplied upon the condition that the persons receiving same will make their own determination as to its suitability for their purposes prior to use. In no event will Alcide Corporation be responsible for damages of any nature whatsoever resulting from the use of or reliance upon such Information. NO REPRESENTATIONS OR WARRANTIES, EITHER EXPRESS OR IMPLIED, OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR OF ANY OTHER NATURE ARE MADE HEREUNDER WITH RESPECT TO THE INFORMATION OR THE PRODUCT TO WHICH THE INFORMATION REFERS.

SANOVA® is the trademark of Alcide Corporation

MSDS  
SANBAS  
REV. 04

A-00045